

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently amended) An acid addition salt of a 5-aminolevulinic acid (5- ALA) derivative ~~(e.g. a 5-ALA ester)~~ with an acid which has a pKa of about 5 or less, ~~preferably about 3 or less~~, wherein said acid is a sulfonic acid, a sulfonic acid derivative, sulfuric acid, nitric acid or phosphoric acid.

2. (Currently amended) An acid addition salt as claimed in claim 1 which is derived from a compound of formula X:



[[[]]]wherein R¹ represents an optionally substituted straight-chained, branched or cyclic alkyl group which may optionally be interrupted by one or more -O-, -NR³-, -S- or -PR³- groups;

R² each independently represents a hydrogen atom or an optionally substituted straight-chained, branched or cyclic alkyl group which may optionally be interrupted by one or more -O-, -NR³-, -S- or -PR³- groups; and

R³ is a hydrogen atom or a C₁₋₆ alkyl group[[[]]].

3. (Currently amended) An acid addition salt as claimed in claim 2, wherein in formula X, R¹ either represents an unsubstituted alkyl group ~~(e.g. C₁₋₆ alkyl)~~ or an alkyl group ~~(e.g. C₁₋₂ alkyl)~~ substituted by an aryl group ~~(e.g. phenyl)~~ and/or each R² represents a hydrogen atom.

4. (Original) An acid addition salt as claimed in claim 2 or claim 3, wherein R¹ is a benzyl or substituted benzyl group.

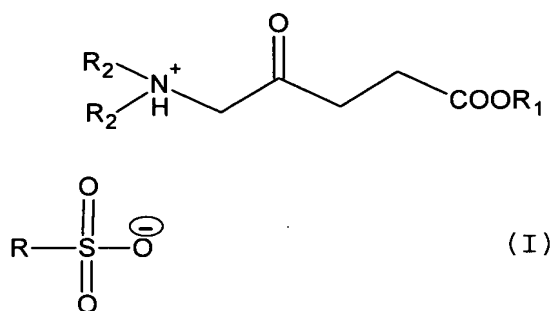
5. (Original) An acid addition salt as claimed in claim 2, wherein said compound of formula X is 5-ALA methyl ester, 5-ALA hexyl ester, 5-ALA benzyl ester, 5- ALA 2-methylpentyl ester, 5-ALA 4-methylpentyl ester, 5-ALA 2-(2-ethoxyethoxy)ethyl ester, 5-ALA 4-methylbenzyl ester or 5-ALA 4-isopropylbenzyl ester.

6. (Original) An acid addition salt as claimed in claim 2, wherein said compound of formula X is 5-ALA methyl ester, 5-ALA hexyl ester or 5-ALA benzyl ester.

7. (Currently amended) An acid addition salt as claimed in ~~any one of claim 1 to 6~~, wherein said acid is an organic acid.

8. (Original) An acid addition salt as claimed in claim 7, wherein said acid is a sulfonic acid or a sulfonic acid derivative.

9. (Currently amended) An acid addition salt as claimed in claim 1 of formula I:



[[~~(I)~~]] wherein R is a hydrogen atom or an optionally substituted alkyl (~~e.g. a C₁₋₂₀-alkyl group~~) or aryl group (~~e.g. an aryl group of up to 20 carbon atoms~~), preferably an optionally substituted alkyl or aryl group;

R¹ represents an optionally substituted straight-chained, branched or cyclic alkyl group which may optionally be interrupted by one or more -O-, -NR³-, -S- or -PR³- groups;

R² each independently represents a hydrogen atom or an optionally substituted straight-chained, branched or cyclic alkyl group which may optionally be interrupted by one or more -O-, -NR³-, -S- or -PR³- groups; and

R³ is a hydrogen atom or a C₁₋₆ alkyl group[[~~(I)~~]].

10. (Original) An acid addition salt as claimed in claim 9, wherein R is optionally substituted phenyl or methyl.
11. (Currently amended) An acid addition salt as claimed in claim 9 or claim 10, wherein in formula I, R¹ either represents an unsubstituted alkyl group (~~e.g. C₁₋₆-alkyl~~) or an alkyl group (~~e.g. C₁₋₂-alkyl~~) substituted by an aryl group (~~e.g. phenyl~~) and/or each R² represents a hydrogen atom.
12. (Currently amended) An acid addition salt as claimed in claim 9, wherein R¹ is a benzyl or substituted benzyl group.
13. (Original) An acid addition salt as claimed in claim 9 which is a sulfonic acid addition salt of 5-ALA methyl ester, 5-ALA hexyl ester, 5-ALA benzyl ester, 5-ALA 2-methylpentyl ester, 5-ALA 4-methylpentyl ester, 5-ALA 2-(2-ethoxyethoxy)ethyl ester, 5-ALA 4-methylbenzyl ester or 5-ALA 4-isopropylbenzyl ester.
14. (Original) An acid addition salt as claimed in claim 9 which is a sulfonic acid addition salt of 5-ALA methyl ester, 5-ALA hexyl ester or 5-ALA benzyl ester.
15. (Original) An acid addition salt as claimed in claim 13 or claim 14, wherein said acid is naphthalene-1,5-disulfonic acid, ethane-1,2-disulfonic acid, p-toluenesulfonic acid, methanesulfonic acid, dodecylsulfonic acid, naphthalene-2-sulfonic acid, benzenesulfonic acid, 2-hydroxy-ethanesulfonic acid, ethanesulfonic acid, or (+)-camphor-10-sulfonic acid.
16. (Currently amended) An acid addition salt as claimed in ~~any one of claim 1 to 6~~, wherein said acid is an inorganic acid.
17. (Currently amended) An acid addition salt as claimed in claim ~~17~~16, wherein said acid is sulfuric acid, nitric acid or phosphoric acid, preferably nitric acid.

18. (Currently amended) An acid addition salt as claimed in ~~any one of claim 1 to 6~~, wherein said acid is a sulfonic acid, a sulfonic acid derivative or nitric acid.
19. (Currently amended) An acid addition salt as claimed in ~~any preceding claim 1~~, wherein said acid is pharmaceutically acceptable.
20. (Currently amended) A process for preparing an acid addition salt as claimed in ~~any one of claim 1 to 19~~, said process comprising reacting a 5-aminolevulinic acid derivative (~~e.g. an ALA ester~~) with an acid as defined in claim 1.
21. (Currently amended) A process for the preparation of an acid addition salt as claimed in ~~any one of claim 1 to 19~~, said process comprising the reaction of 5-aminolevulinic acid, or an esterifiable derivative thereof, with an alkanol or an ester-forming derivative thereof (~~e.g. with an alkanol~~) in the presence of an acid as defined in claim 1.
22. (Currently amended) A process for the preparation of an acid addition salt as claimed in ~~any one of claim 1 to 19 (e.g. a compound of formula I)~~, said process comprising:
 - (i) contacting a solution comprising a hydrochloride salt of an ALA derivative (~~e.g. a compound of the formula $\text{Cl}^- \text{R}^2_2 \text{N}^+ \text{H}-\text{CH}_2\text{COCH}_2\text{CH}_2\text{CO}_2\text{R}^1$ wherein R^1 and R^2 are as defined in claim 2~~) with a basic anion exchange resin;
 - (ii) optionally removing said resin; and
 - (iii) mixing the resulting solution with a solution comprising an acid as defined in claim 1 ~~preferably a sulfonic acid or a sulfonic acid derivative~~.
23. (Currently amended) A process for the preparation of an acid addition salt as claimed in ~~any one of claim 1 to 19 (e.g. a compound of formula I)~~, said process comprising:
 - (i) reacting a hydrochloride salt of an ALA derivative (~~e.g. a compound of the formula $\text{Cl}^- \text{R}^2_2 \text{N}^+ \text{H}-\text{CH}_2\text{COCH}_2\text{CH}_2\text{CO}_2\text{R}^1$ wherein R^1 and R^2 are as defined in claim 2~~) with a silver salt of an acid as defined in claim 1, ~~preferably a sulfonic acid or a sulfonic acid derivative~~, in a solvent in which AgCl is substantially insoluble; and
 - (ii) optionally separating AgCl from the resulting salt.
24. (Currently amended) An acid addition salt obtainable by contacting (~~e.g. reacting~~) a 5-ALA derivative (~~e.g. a 5-ALA ester~~) with an acid as defined in claim 1.
25. (Currently amended) A An acid addition salt obtainable by a process as claimed in ~~any one of claim 20 to 23~~.
26. (Currently amended) A pharmaceutical composition comprising an acid addition salt as claimed in ~~any one of claim 1 to 19, 24 or 25~~, together with at least one pharmaceutical carrier or excipient.
27. (Currently amended) An acid addition salt as claimed in claim 1 or composition as claimed in ~~any one of claim 1 to 19, 24, 25 or 26~~ for use as a medicament, ~~e.g. for use in photodynamic therapy~~.
28. (CANCELLED)
29. (Currently amended) A method of photochemotherapeutic treatment of disorders or abnormalities of external or internal surfaces of the body, said method comprising administering to the affected surfaces, an acid addition salt as claimed in claim 1 or composition as claimed in ~~any one of claim 1 to 19, 24, 25 or 26~~, and exposing said surfaces to

light (e.g. white light), preferably to light in the wavelength region 300-800 nm (e.g. blue light in the wavelength region 380-440 nm).

30. (Currently amended) A product comprising an acid addition salt as claimed in ~~any one of claim 1 to 19, 24, 25 or 26~~, together with at least one surface-penetration assisting agent, and optionally one or more chelating agents as a combined preparation for simultaneous, separate or sequential use in treating disorders or abnormalities of external or internal surfaces of the body which are responsive to photochemotherapy.
31. (Currently amended) A kit for use in photochemotherapy of disorders or abnormalities of external or internal surfaces of the body comprising:
- a) a first container containing an acid addition salt as claimed in ~~any one of claim 1 to 19, 24, 25 or 26~~,
 - b) a second container containing at least one surface penetration assisting agent; and optionally
 - c) one or more chelating agents contained either within said first container or in a third container.
32. (Currently amended) A method of in vitro diagnosis of abnormalities or disorders by assaying a sample of body fluid or tissue of a patient, said method comprising at least the following steps:
- i) admixing said body fluid or tissue with an acid addition salt as claimed in ~~any one of claim 1 to 19, 24, 25 or 26~~, ii) exposing said mixture to light,
 - iii) ascertaining the level of fluorescence, and
 - iv) comparing the level of fluorescence to control levels.
33. (New) A method of treating a condition that is responsive to photochemotherapy comprising administering to an area of the body affected by said condition an acid addition salt as claimed in claim 1.
34. (New) The acid addition salt as claimed in claim 1 wherein the 5-aminolevulinic acid derivative is a 5-ALA ester.
35. (New) The acid addition salt as claimed in claim 1 wherein the acid has a pKa of about 3 or less.
36. (New) An acid addition salt as claimed in claim 3, wherein R¹ represents an unsubstituted C₁₋₆ alkyl or a C₁₋₂ alkyl substituted by an aryl group.
37. (New) An acid addition salt as claimed in claim 35, wherein the C₁₋₂ alkyl substituent is phenyl.
38. (New) An acid addition salt as claimed in claim 9, wherein R represents an optionally substituted C₁₋₂₀ alkyl group or an optionally substituted aryl group of up to 20 carbon atoms.
39. (New) An acid addition salt as claimed in claim 11, wherein R¹ represents an unsubstituted C₁₋₆ alkyl or a C₁₋₂ alkyl substituted by an aryl group.
40. (New) An acid addition salt as claimed in claim 38, wherein the C₁₋₂ alkyl substituent is phenyl.
41. (New) A process as claimed in claim 20, wherein the 5-aminolevulinic acid derivative is an ALA ester.

42. (New) A process as claimed in claim 21, wherein the ester-forming derivative is an alkanol.
43. (New) A process as claimed in claim 22, wherein the acid addition salt is a compound of formula I.
44. (New) A process as claimed in claim 22, wherein the hydrochloride salt of an ALA derivative is a compound of the formula $\text{Cl}^- \text{R}^2 \text{N}^+ \text{H} - \text{CH}_2 \text{COCH}_2 \text{CH}_2 \text{CO}_2 \text{R}^1$, wherein
- R^1 represents an optionally substituted straight-chained, branched or cyclic alkyl group which may optionally be interrupted by one or more $-\text{O}-$, $-\text{NR}^3-$, $-\text{S}-$ or $-\text{PR}^3-$ groups;
- R^2 each independently represents a hydrogen atom or an optionally substituted straight-chained, branched or cyclic alkyl group which may optionally be interrupted by one or more $-\text{O}-$, $-\text{NR}^3-$, $-\text{S}-$ or $-\text{PR}^3-$ groups; and
- R^3 is a hydrogen atom or a C_{1-6} alkyl group.
45. (New) A process as claimed in claim 22, wherein in step (iii) the acid is a sulfonic acid or a sulfonic acid derivative.
46. (New) A process as claimed in claim 23, wherein the acid addition salt is a compound of formula I.
47. (New) A process as claimed in claim 23, wherein the hydrochloride salt of an ALA derivative is a compound of the formula $\text{Cl}^- \text{R}^2 \text{N}^+ \text{H} - \text{CH}_2 \text{COCH}_2 \text{CH}_2 \text{CO}_2 \text{R}^1$, wherein
- R^1 represents an optionally substituted straight-chained, branched or cyclic alkyl group which may optionally be interrupted by one or more $-\text{O}-$, $-\text{NR}^3-$, $-\text{S}-$ or $-\text{PR}^3-$ groups;
- R^2 each independently represents a hydrogen atom or an optionally substituted straight-chained, branched or cyclic alkyl group which may optionally be interrupted by one or more $-\text{O}-$, $-\text{NR}^3-$, $-\text{S}-$ or $-\text{PR}^3-$ groups; and
- R^3 is a hydrogen atom or a C_{1-6} alkyl group.
48. (New) A process as claimed in claim 23, wherein in step (i) the acid is a sulfonic acid or a sulfonic acid derivative.
49. (New) An acid addition salt as recited in claim 24 wherein the ALA derivative is a 5-ALA ester.
50. (New) The method of claim 29 wherein the light is white light, light in the wavelength region 300-800 nm, or blue light in the wavelength region 380-440 nm.